K003548

SEP - 4 2001

EXHIBIT 1

PadPro LLC.
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Contact: Cliff Poppy, President

June 12, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "PadPro System" Defibrillator Electrode Adapters

2. Classification Name/Product Code: DC-defibrillator, maximum 360 joules; LDD, Product Class II and Class III, MKJ.
   Common/Usual Name: Defibrillator Electrode Adapter

3. Equivalent legally marketed device: This similar in function to the Hewlett Packard Heartstream (K984286)

4. Indications for Use: For use with disposable electrodes for automatic and manual external defibrillators for monitoring, pacing, and defibrillation.

5. Description of the Devices: The PadPro System Adapters are used to adapt the original equipment cable set to allow the use of disposable defibrillator electrode pads The adapters plug into the end of the OEM's "therapy cable". This allows us to keep the equipment (cable) intact and provides the user with an interface to our disposable electrode. The second approach is to reterminate the OEM's cable with our connector. Both methods are employed and frequently each hospital will use a combination of the two.

Make and Model	PadPro Adapter Catalog #s
Agilent Technologies Models:	
Codemaster	HP
HeartStream	HP4R
Zoll Models:	
1200	Zoll
1400	Zoll
2000	Zoll
M-Series	Zoll
Physio-Control Models:	
LP-9	Quick
LP-10	Quick
LP-12	Quick
Quick Pace	
Cardiotronics	
R2	R2
Cardiotronics	Cardio

Total # of unique adapters: 6

6. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Hewlett Packard Heartstream Electrode Adapter K984286	"PadPro System" Defibrillator Electrode Adapters
Indications for use	For use with disposable electrodes for automatic and manual external defibrillators for monitoring, pacing, and defibrillation	SAME
Where used	Hospitals and all locations where automatic or manual external defibrillators may be used	SAME
Standard met	International Electrotechnical Commission (IEC) 601-1: Medical Electrical Equipment 601-1 (1988) Part 1: General requirements for safety	SAME

7. Summary of performance tests: The following shows measurements made using various makes of low energy defibrillators, with and without the adapters, tested at 100J and 360J. The data clearly demonstrates no drop off in energy delivered.

Hewlett Packard				**Measure**			
	Settings	# 1	# 2	# 3	# 4	# 5	Average
Baseline	100j	103.2j	103.2j	103.0j	102.7j	103.2j	103.06j
Adapted	100j	102.7j	102.9j	102.5j	102.5j	102.3j	102.58j
Verification		102.9j	102.6j	102.7j			102.73j
Baseline	360j	366.4j	365.6j	367.2j	366.0j	367.3j	366.50j
Adapted	360j	368.3j	365.1j	367.8j	363.9j	365.8j	366.18j
Verification		366.6j	368.0j	366.3j			366.97j
Physio Control				**Measure**			
	Settings	# 1	# 2	# 3	# 4	# 5	Average
Baseline	100j	99.0j	99.0j	99.4j	100.8j	98.9j	99.42j
Adapted	100j	99.3j	99.2j	99.2j	99.6j	99.6j	99.38j
Verification		98.8j	98.9j	99.1j			98.93j
Baseline	360j	356.7j	357.0j	356.1j	356.1j	354.8j	356.14j
Adapted	360j	356.4j	355.7j	354.5j	354.2j	354.1j	354.98j
Verification		353.9j	354.5j	354.2j			354.2j
Zoll				**Measure**			
	Settings	# 1	# 2	# 3	# 4	# 5	Average
Baseline	100j	103.8j	104.2j	104.3j	103.1j	103.0j	103.68j
Adapted	100j	103.3j	105.8j	104.4j	103.3j	103.7j	104.10j
Verification		103.4j	103.5j	104.2j			103.71j
Baseline	360j	365.5j	368.6j	367.4j	369.0j	363.3j	366.76j
Adapted	360j	363.3j	370.0j	365.1j	366.3j	368.2j	366.58j
Verification		366.8j	367.1j	366.4j			366.81J
Laerdal				**Measure**			
	Settings	# 1	# 2	# 3	# 4	# 5	Average
Baseline	100j	98.0j	99.5j	100.2j	100.0j	97.0j	98.94j
Adapted	100j	99.0j	98.1j	99.2j	99.0j	99.3j	98.92j
Verification		98.6j	98.2j	99.4j			98.73j
Baseline	360j	362.8j	360.2j	365.7j	365.9j	364.1j	363.74j
Adapted	360j	369.2j	367.5j	366.1j	365.0j	363.0j	366.16j
Verification		365.8j	366.1j	365.3j			365.73j

8. Conclusion: In all respects, the PadPro System Defibrillator Electrode Adapters are substantially equivalent to other adapters that are legally marketed for this purpose. The device meets the performance standard referenced above. 100% testing for mating/unmating force, electrical resistance, and dielectric strength at 5000 volts assures safe and effective electrode adapters. Where applicable, original equipment cables are employed in the manufacture of these adapters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2001

PadPro LLC.
c/o Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K003548
Trade Name: PadPro System Defibrillator Electrode Adapters
Regulatory Class: III (three)
Product Code: MKJ
Dated: March 18, 2001
Received: March 21, 2001

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4369. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K003548

Device Name: "PadPro System" Defibrillator Electrode Adapters.
Indications for Use: For use with disposable electrodes for automatic and manual external defibrillators for monitoring, pacing, and defibrillation

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003548